EXHIBIT 3

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCTS LIABILITY
LITIGATION MDL NO. 2327

DARLA FLOWERS,

Plaintiff,

vs. Case No.
2:13-cv-6764

ETHICON, INC., et al.,

Defendants.

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December 13, 2013

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Videotaped deposition of RICHARD WOODRUFF, MD, held at Safety Harbor Resort & Spa, 105 North Bayshore Drive, Safety Harbor, Florida, commencing at 9:42 a.m., on the above date before Rhonda Hall-Breuwet, RMR, CRR, FPR, CLR, Realtime Systems Administrator

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VIDEOGRAPHER:
RON FLEMING

Flowers, plaintiff, versus Ethicon, defendants."

Do you see that?

A. Yes.

Q. Okay. Do you understand that Ethicon is the manufacturer of the Prolift with device?

A. Yes.

Q. And do you understand that the Prolift anterior device is the device that you implanted into Darla Flowers in 2007?

A. Yes.

Q. And you may observe this from the caption, but you understand that Darla Flowers is not suing you or bringing any sort of legal action against you whatsoever?

A. Yes, I understand that.

Q. And do you understand that Darla is not alleging that you did anything wrong in this case?

A. Yes.

Q. Let's go to page 3, which is Exhibit A. I'm going to cover a couple

that a risk might happen and the time spent counseling with a patient?

A. Yes.

Q. With regard to the severity of a risk and how severe the risk might be, is there some correlation between the amount of time spent counseling with a patient?

A. Yes.

Q. And is it true to say that the more severe the risks can be, the more you'd want to spend time counseling with a patient about the risks?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. Let me talk to you about the FDA for just a minute.

In your experience as -- and strike that.

First, you have some experience -- I mean, this may be fairly obvious, but just to get some background here, you obviously have some experience

implanting medical devices into patients.

A. Yes.

Q. And when -- during your practice, when you were implanting medical devices into patients, did you have some understanding that the medical devices had been looked at by a governmental agency?

A. Yes.

Q. Did you have some understanding of the FDA and what the FDA did?

A. Yes.

Q. And just generally speaking, explain for the jury, what was your understanding of what the FDA does with regard to medical devices?

A. Well, the FDA, to my knowledge, looks at the data presented by the manufacturers and approves or disapproves the product.

Q. And during your practice, if a sales representative or otherwise some other company representative presented a medical device to you, what was your

presumption as it pertains to FDA clearance or approval?

MS. METZGER: Object to form.

THE WITNESS: My assumption was that it had been approved.

BY MR. PRICE:

Q. And why would a doctor presume that if a medical device being presented by a sales representative had been -- I'm sorry. I lost my train of thought.

As a doctor, a sales representative presents a medical device to you, it may seem obvious, but why would you presume that it's cleared by the FDA?

MS. METZGER: Object to form.

THE WITNESS: Well, I'm going to elaborate on this.

BY MR. PRICE:

Q. Sure.

A. I can't answer it with a yes or no.

Q. Sure.

A. We would have -- and this is not a device, but medications, you know, we would have pharmaceutical reps come in and they would tell us, "We've got a new product in the pipeline. Can't talk about it yet because it's not FDA approved." And they wouldn't tell us anything -- they would say it's -- like a new birth control pill. "Can't talk about it yet because's not FDA approved. It's going to be exciting, but can't say any more about it until we get FDA approval."

So they wouldn't tell us anything more than just "new birth control pill; it's going to be exciting, and we'll tell you about it as soon as we get FDA approval."

So, you know, we were -- we would assume that products that were presented to us were FDA approved.

Q. And to your knowledge, were you ever presented a product or medication that was not approved by the

FDA that you then used in a patient?

A. Well, certainly not to my knowledge.

Q. And if the representative presented to you a product and told you that it had not been cleared by the FDA, what would your reaction be?

MS. METZGER: Object to form.

THE WITNESS: Well, I don't think I would use something that hadn't been cleared by the FDA.

BY MR. PRICE:

Q. Let's talk about your experience with the Prolift device specifically.

When was the first time that you can recall that you heard of this Prolift device?

A. Probably sometime during the -- either the summer or fall of 2005.

Q. Do you recall what method it was presented to you?

A. I think the sales rep brought information around.

Q. And does Exhibit 9 look familiar to you?

A. Yes.

Q. And describe what Exhibit 9 is.

A. It's the -- you referred to it as the IFU. I'm not sure what that stands for, but it's the product insert.

Q. It's the documentation that comes with the --

A. With the kit.

Q. -- with the Prolift kit?

A. Yes.

Q. And it would be your practice to review the documentation contained within the Prolift kit?

A. Not every time because it's redundant, but the first time, second time. After that, you know it.

Q. Sure. And occasionally if you needed to refresh any of the information contained within the instructions for use of the product insert, would you have the product insert and review it in case you needed to

refresh your recollection on anything?

A. Yes.

Q. But, indeed, you have before --

A. Yes.

Q. -- read this and --

A. Yes.

Q. -- read it completely before using the Prolift --

A. Yes.

Q. -- device?

I want to point your attention to a few specific things. We're not going to sit and read the whole thing today, but I want to point out to you a few things and get some clarification.

Let's go to the page after the first page, which, for the record, is ETH.MESH.02341523.

Are you on that page, Doctor?

A. Yes.

Q. It says, "Please read all information carefully."

Do you see that?

A. Yes.

Q. Did you indeed, at least before you started implanting Prolift devices, read the information in the IFU correctly?

A. Yes.

Q. Carefully. Excuse me.

A. Yes.

Q. And the third paragraph says, "Training on the use of the Gynecare Prolift." Do you see where it says that?

A. Yes.

Q. It says, "Training on the use of the Gynecare Prolift pelvic floor repair systems is recommended and available. Contact your company sales representatives to arrange for this training."

Did I read that correctly?

A. Yes.

Q. And did you indeed follow through and receive training on the Gynecare Prolift as is instructed here?

A. Yes.

Q. Under "Indications," can you read the indications section where it says "The Gynecare Prolift total"? Do you see where I'm reading?

A. Yes.

Q. Read with me. "The Gynecare Prolift total anterior and posterior pelvic repair systems are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor and vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect."

Do you see that?

A. Yes.

Q. And referring specifically to Darla Flowers' case, did you use the Prolift in Darla Flowers' case as is indicated in this instruction for use?

A. Yes.

Q. And it talks about some components here. To be specific, in

patients?

MS. METZGER: Object to form.

THE WITNESS: We would have spent more time on that.

BY MR. PRICE:

Q. What about 10 percent? Is that high enough for you? Would it have altered the way you discuss the risk of erosion or extrusion with your patients?

A. I think we would have spent a little more time talking about it, yes.

Q. What about any risks of sexual dysfunction or dyspareunia associated with any of these risks?

MS. METZGER: Object to form.

BY MR. PRICE:

Q. Is it fair to say that in 2007 you had no understanding of any sexual dysfunction risk associated with the Prolift device?

A. That was an issue that wasn't discussed in any of the training that I went to, and at least in the

initial follow-up that I had with patients in the first two years, there was actually improvement in sexual function. It was only when I started seeing erosions later that it became an issue.

Q. And the issue of the risk of sexual dysfunction and dyspareunia, if a company like Ethicon had the knowledge of an increased risk of that, would you like to know that as a physician?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. Would you then pass that information on to your patients?

A. Yes.

MS. METZGER: Object to form.

BY MR. PRICE:

Q. If there were any warnings here in the adverse reactions section that discussed sexual dysfunction, including dyspareunia, would you have

spent time talking to your patients about that risk?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. Would you weigh the risk of sexual dysfunction, including dyspareunia, against any perceived benefits of the Prolift device?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. The last -- after erosion/exclusion, it discusses scarring that results in implant contraction. Do you see that?

A. Yes.

Q. Did you have any understanding as to the rate of implant contraction that may occur after implantation of the Prolift device?

MS. METZGER: Object to form.

THE WITNESS: Again, I don't think that was discussed.

BY MR. PRICE:

Q. It's correct to say, you knew that you needed to implant the device with some correct tension? Is that fair?

A. Yes.

Q. And the tension that you placed in Darla Flowers' case was based on your experience in implanting other Prolift devices?

A. Yes.

Q. And before you started implanting other Prolift devices, did you learn how to implant Prolift devices from training by Ethicon?

A. Yes. And, actually, it's more proper to say "tension-free," not "tension."

Q. Let me ask you about any risk of mesh degradation. Were you ever told by Ethicon that the Prolift mesh posed a possibility of mesh degradation?

MS. METZGER: Object to

form.

THE WITNESS: No.

BY MR. PRICE:

Q. Were you ever told that the mesh could degrade in the Prolift to the point that the mesh loses structural integrity?

MS. METZGER: Object to form.

THE WITNESS: No.

BY MR. PRICE:

Q. What about mesh bunching in the vagina? Did you ever hear about the risk of mesh bunching in the vagina from Ethicon?

MS. METZGER: Object to form.

THE WITNESS: No.

BY MR. PRICE:

Q. What about mesh curling in the vagina? Did you ever hear any warnings of mesh curling in the vagina from Ethicon?

MS. METZGER: Same objection.

THE WITNESS: No.
BY MR. PRICE:
Q. What about mesh contraction? Did you ever hear about any risks of mesh contraction after implantation of the Prolift, from Ethicon?
MS. METZGER: Object to form. He just testified that that was in the IFU.
MR. PRICE: I'll strike that. Actually, we did cover mesh contraction just a moment ago. I would dispute that he testified that that was in the IFU, but I'll strike that. We did discuss contraction.
BY MR. PRICE:
Q. What about mesh banding? Do you have an idea of what mesh banding is?
A. Yes.
Q. And how do you have an idea as to what mesh banding is?
A. Well, that's when you can feel one of the arms on pelvic exam.
Q. Are you talking about after

implantation?

A. After the implantation, yes. When you see a patient back for a routine exam, you can feel one of the arms.

Q. Was it ever discussed with you by Ethicon that there might be a banding effect of the arms after implantation of the Prolift mesh?

MS. METZGER: Object to form.

THE WITNESS: No.

BY MR. PRICE:

Q. What about permanent nerve pain? Did Ethicon ever warn you that there might be permanent nerve pain associated with implantation of the Prolift device?

MS. METZGER: Same objection.

THE WITNESS: Not that I recall.

BY MR. PRICE:

Q. If you recall -- if Ethicon were to tell you that there could be permanent nerve pain associated with the

Prolift device, do you think that would stand out to you?

A. I would think so, yes.

Q. Let's talk about some of Darla Flowers' medical charts. I'm going to -- do you mind if we go off the record for just a moment?

A. Sure.

THE VIDEOGRAPHER: The time is 11:49 a.m. Off the record.

(Off the record from 11:49 a.m. to 11:59 a.m.)

THE VIDEOGRAPHER: The time is 11:59 a.m. On the record.

(Document was marked as Plaintiff's Exhibit Number 10 for identification.)

(Document was marked as Plaintiff's Exhibit Number 11 for identification.)

BY MR. PRICE:

Q. Welcome back, Dr. Woodruff. For the record, you have in front of you Exhibit 10 and Exhibit 11. Correct?

A. Yes.

A. 13, yeah.
Q. Exhibit 13 is the FDA's July 2011 warning. Have you ever seen Exhibit 13 before?
A. Yesterday.
Q. Okay. So when I showed it to you yesterday when we sat down and met?
A. Yes. There was after I retired.
Q. Yeah. So you -- did you -- you didn't have an opportunity to read it until yesterday because you -- you've been retired?
A. Correct.
Q. So is it fair to say that your review of literature has slowed down since you've retired?
A. Yes.
Q. And after reading this -- after I showed it to you yesterday, did you have any impressions regarding this FDA 2011 announcement?
A. No. The important thing I think is that the complications are not

that rare.

Q. As a physician back in 2007, if you would have read an announcement that said complications associated with transvaginal mesh repair of prolapse are not rare, would that have affected the way you counseled your patients?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. Would you have spent more time talking about complications with your patients?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. Would you have specifically spent more time talking about the complications of erosion?

MS. METZGER: Object to form.

THE WITNESS: Yes.

* * *

BY MR. PRICE:

Q. Would you have spent more time talking about the complications of sexual interference such as dyspareunia, painful intercourse?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. Dr. Woodruff, would you -- would you question the integrity of a medical device that had not been approved by the FDA?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. If you found out that a medical device had not been approved by the FDA, would you want the manufacturer to do more research before you -- before you used the product?

MS. METZGER: Same objection.

THE WITNESS: Yes.

BY MR. PRICE:

Q. Would you want the product to be FDA-approved before you used it?

A. Yes.

MS. METZGER: Object to form.

BY MR. PRICE:

Q. Do you have an understanding that the Prolift device was not actually cleared by the FDA until after you implanted it in Darla Flowers?

MS. METZGER: Object to form.

THE WITNESS: I know that now.

BY MR. PRICE:

Q. You didn't know that back in 2007 when you implanted it?

A. No.

MS. METZGER: Object to form.

BY MR. PRICE:

Q. Let me show you briefly Exhibit 17 -- excuse me -- Exhibit 14.

A. 14.

(Document was marked as Plaintiff's Exhibit Number 14 for identification.)

BY MR. PRICE:

Q. This is a public record. And I just want to point your attention to some of the dates in this record. It's a -- take a look and skim through that. I presume you've not seen that document before?

MS. METZGER: I'm going to object to the use of these at the deposition because I know that we've produced them in some form to you. Are you representing that you got these through a Freedom of Information Act request?

MR. PRICE: I'm representing that I got them through public information sources. This particular copy that I'm showing you is not -- I'm not saying that that's an Ethicon document.

MS. METZGER: Are you willing to represent where it is

that you got the copy of the document that you're showing the doctor?

MR. PRICE: Sure. I got it online. If my recollection serves me correctly, I got it from the FDA Web site. But --

MS. METZGER: Okay.

MR. PRICE: My recollection's not necessarily 100 percent, but that's my best recollection sitting here today.

MS. METZGER: To the extent that either of these two documents are not publicly available -- and I haven't checked your source, so I don't know whether they're obtainable from that source -- then I object to the use at the deposition because they weren't previously identified to us as required by PTO 38, and move to strike any testimony related to these documents.

MR. PRICE: And, Dr.

Woodruff, you can go ahead -- the source -- I mean, the PTO 38 provision that you're referencing, is that the Ethicon production provision?

MS. METZGER: It's the 48 hours in advance of a treating physician deposition, you need to disclose to us the documents that you're going to use at the deposition.

MR. PRICE: Right. Right. And for the record, this -- this particular copy that I'm using is not a Ethicon-produced document. I got it through public sources.

MS. METZGER: I will just continue my objection. If it turns out to be an issue, we'll deal with it.

MR. PRICE: Sure.

BY MR. PRICE:

Q. Have you had a chance to look through that, Doctor?

A. Yes.

Q. I'm directing your attention to the third page, the Department of Health and Human Services as the cover page. The recipients of this letter appears to be Ethicon, Inc.; is that correct?

A. Yes.

Q. And Ethicon, Inc., is the manufacturer of the Prolift device?

A. Yes.

Q. And you see there's a date stamp there, May 15th, 2008?

A. Yes.

Q. Do you see that? And under the "re" section, R-E, that gives trade/device names. Gynecare Prolift, do you see that name there?

A. Yes.

Q. It says, "Gynecare Prolift Total, Anterior, and Posterior Pelvic Floor Repair Systems."

Do you see that?

A. Yes.

Q. Are these repair systems repairs systems that you were using in

Q. Correct?
A. Yes.
Q. So it's fair to state that under your standards as a doctor, you would not use a device that was not FDA-approved?
MS. METZGER: Object to --
BY MR. PRICE:
Q. Is that fair?
MS. METZGER: Object to form to the continued leading nature of these questions.
THE WITNESS: I would have preferred that it would have been FDA-approved.
BY MR. PRICE:
Q. Do you understand that in 2012 the -- strike that.
Do you understand that after the FDA's notification in 2011, that the FDA approached Ethicon and asked them to do further studies on the Prolift product?
MS. METZGER: Object to form.

THE WITNESS: Yes.
BY MR. PRICE:
Q. How did you obtain that understanding?
A. You informed me of that yesterday.
Q. Did -- were you surprised to hear that, that they were asked by the FDA to do 522 studies?
A. No.
Q. And why does that not surprise you?
A. Well, the FDA is looking for evidence that the risk-benefit ratio with that product is reasonable.
Q. Do you yourself question the risk-benefit ratio of the Prolift product?
MS. METZGER: Object to form.
THE WITNESS: In general. I'm not going to limit it to Prolift. I think that there still is a place for mesh-enhanced vaginal surgery.

BY MR. PRICE:

Q. But the indications for that surgery, the risks and benefits must be --

A. Balanced.

MS. METZGER: I'm going to object to form.

BY MR. PRICE:

Q. The risks and benefits must be balanced?

MS. METZGER: Same objection.

THE WITNESS: Yes.

BY MR. PRICE:

Q. I'm handing you what's been marked as Exhibit 15.

(Document was marked as Plaintiff's Exhibit Number 15 for identification.)

BY MR. PRICE:

Q. Take a look at Exhibit 15. Have you seen that letter before?

A. Yes.

Q. Did I show you that letter when we met?

A. Yes.
Q. It was the first time you had seen that letter, right?
A. Yes.
Q. Did you have a chance to take a look at it and read through it?
A. Yes.
Q. I want to ask you a couple questions about it.
On the second page of the letter -- well, actually, let me back up.
The first page of the letter begins a section that says, "Accordingly, under Section 522 of the act, we are ordering you to conduct a postmarket surveillance study of your device to address our questions below."
Do you see that?
A. Yes.
Q. Now, these appear to be questions asked by the Department of Health and Human Services to Ethicon; is that correct?
A. Yes.
MS. METZGER: Object to

form.

BY MR. PRICE:

Q. The second one says, "What are the rates associated with each of the following adverse events through 36 months post-implant: mesh exposure in the vagina, mesh erosion into another organ, pelvic pain, infection, de novo dyspareunia, vaginal shortening, vaginal scarring, de novo vaginal bleeding, atypical vaginal discharge, fistula formation, de novo voiding dysfunction (including de novo incontinence), neuromuscular problems (including groin and leg pain), revision surgery, recurrent prolapse."

Do you see that?

A. Yes.

Q. And the FDA appears to be asking, "What are the rates associated with these complications?" right?

MS. METZGER: Object to form.

THE WITNESS: Yes.

* * *

BY MR. PRICE:

Q. And as a practicing doctor, would it be important for you to understand what are the rates of these complications of the devices that you're implanting into your patients?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. And if Ethicon had the ability to obtain that information before marketing the Prolift device, would you have liked to know that information when you were discussing the risks and benefits with your patients?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. The third question is, "What is the quality of life (including sexual function) for women who have received this device at 6 months, 12 months, 18 months, 24 months, and 36 months

post-surgery?"

Do you see that?

A. Yes.

Q. Is that the type of question that you would like to -- strike that.

If Ethicon had the ability to find that information, would you like to know that information before you implanted the Prolift into your patients?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. Is the quality of life, including sexual function, the type of information that you would consider in a risk-benefit analysis for your patients?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. Number 5, "Among patients with resurgery within 36 months after transvaginal pelvic organ prolapse" -- strike that. Reading problems today.

"Among patients with resurgery within 36 months after initial transvaginal pelvic prolapse surgery with the mesh:

"a. what are the rates of adverse events and what is the quality of life during the . . . following resurgery?"

Do you see that?

A. Yes.

Q. And if resurgery was a common occurrence after implantation of the Prolift device, would you like to know that, as a doctor?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. Would you like to know the rates of adverse events as it pertains to any resurgeries that had occurred with the Prolift device?

MS. METZGER: Object to form.

THE WITNESS: Could you

rephrase that?
BY MR. PRICE:
Q. Sure. In 2007, if Ethicon was in a position to know how many resurgeries had occurred with the Prolift device, would you like to know that before implanting the Prolift into Darla Flowers?
MS. METZGER: Object to form.
THE WITNESS: Yes.
BY MR. PRICE:
Q. You would take into consideration whether or not Darla would need subsequent resurgeries for the Prolift device, wouldn't you?
A. Yes.
MS. METZGER: Object to form.
BY MR. PRICE:
Q. If after being asked this information by the FDA, if Ethicon then decided to withdraw the Prolift product instead of following through with the FDA's 522 studies, would that cause you

intended to use at the deposition.

In the e-mail, I said I didn't guarantee I was going to use all these documents, but this was on the list of those documents. So that's just -- I wanted to put that on the record.

BY MR. PRICE:

Q. So you have Exhibit 16 in front of you?

A. I do.

Q. Okay. And when we left off, we were talking about the 522 studies of Ethicon. So let's flip to the e-mail. It starts on page ETH.MESH.05603796.

Are you there?

A. Yes.

Q. There's an e-mail among two people among -- well, actually among several people. I want to point your attention to the verbiage "As I read Section 10 of this guidance." Are you with me?

A. Yes.

Q. It says, "As I read Section

10 of this guidance, a company may not have to perform the 522 study if the product is withdrawn from the market. I'm not sure if the product can be withdrawn after the 522 order is received or if the option not to conduct the study only applies to products that were withdrawn before the issuance of the 522 order.

"We will need to get further clarity on our options going forward."

Do you see that?

A. Yes.

Q. Now, if one of the considerations of Ethicon was to opt to not going forward with the 522 study instead of following through with the FDA's request, would it raise a concern with you as to the integrity of the product that you had used before?

MS. METZGER: Object to form. And over my previous objection that if indeed this document had not been previously produced to us, I object to its

use and move to strike any testimony regarding it.

But over those objections, Doctor, please answer if you can.

MR. PRICE: Okay. And Kim, if you wouldn't mind, I can -- for the rest of the questions on this document, we can do a running objection --

MS. METZGER: Running objection?

MR. PRICE: -- for that.

MS. METZGER: That's fine. Thank you.

I'll also object to the form of the question.

BY MR. PRICE:

Q. Do you need me to repeat the question after that?

A. Please.

Q. Okay. And this may not be the exact rephrasing, but basically the question is: If Ethicon, after being asked by the FDA to perform 522 studies, considered not going forward with the 522

studies and the information asked with regard to patient safety, would you have some concerns about the Prolift product's integrity?

MS. METZGER: Object to form.

THE WITNESS: Well, it would raise a question, yes.

BY MR. PRICE:

Q. Dr. Woodruff, we've talked about some of the complications and risks of the Prolift procedure in 2007 versus what you know today.

Do you recall our general discussion of that?

A. Yes.

Q. And you also recall we discussed that you heightened some of your discussions with patients with regard to risk and benefits even after the FDA's 2008 warning; is that accurate?

A. Yes.

Q. And assuming you were practicing today, after reading the July 2011 warning, would you likely

heighten your risk-benefit discussion even more after reading that?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. So knowing what we know today, going back in 2007, if you would have had that information with regard to risks of erosion, risks of sexual complications, and any other risks that you were not aware of, would you go back and have a heightened discussion with Darla Flowers about the risks and benefits of the Prolift device?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. And is there a possibility that that heightened discussion would lead to a different decision as to whether or not to implant the Prolift device in Darla Flowers?

MS. METZGER: Object to

form. Calls for speculation as to what Ms. Flowers would have decided.

THE WITNESS: I think it's hard to say what she would have decided. I would have to agree that I have no idea what she would have decided. It's possible that she may have been willing to accept the risk. I don't know.

BY MR. PRICE:

Q. Fair enough. But you can say that you know today that you would have spent more time talking about the risk of complication?

A. Yes.

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. And it's also fair to say that you would have spent much more time discussing the degree of problems associated with her prolapse decisions so that you could weigh those against those

heightened risks that we've discussed about today?

MS. METZGER: Object to form.

THE WITNESS: Yes.

MR. PRICE: That's all I have. Thank you, Doctor. I may have some more questions after defense finishes, but it's now her turn.

CROSS-EXAMINATION

BY MS. METZGER:

Q. Good afternoon, Doctor.

A. Good afternoon.

Q. My name is Kim Metzger. I represent Johnson & Johnson and Ethicon in this lawsuit, and we met for the first time today; is that correct?

A. Yes.

Q. You did not meet Mr. Price for the first time today, though, right?

A. Correct.

Q. When did you first meet with Mr. Price?

A. Yesterday.

Q. Can you tell me about that meeting, please.

A. He wanted to meet with me yesterday just to familiarize me with what this was going to be like and -- you know, I had not seen the chart for six years -- so I could review the chart.

Q. How long did you meet with Mr. Price yesterday?

A. An hour maybe.

Q. And had you spoken with him or anybody from his office on the telephone before meeting with him yesterday?

A. Yes.

Q. And how many times did you speak with Mr. Price on the phone or someone from his office?

A. I think I initially talked with his paralegal to set up a date. I think her name is Brandi.

THE WITNESS: Is that right?

MR. PRICE: Yeah. Actually, that's right.

THE WITNESS: And I think I

MR. PRICE: Object to form. Sorry.

THE WITNESS: Yes.

BY MS. METZGER:

Q. You met with Mr. Price for an hour, and did he do more than show you the charts and the medical records?

A. He asked me some of the same questions that he asked me today.

Q. Did he ask you how you were going to answer those questions?

A. No.

Q. What questions do you recall that he asked you today that he also asked you yesterday? You can do it in terms of general subject matter, that sort of thing first, and we'll see if we need to go deeper.

A. I mean, basically, he kind of went through the whole outline of what he was going to ask me.

Q. So he took your deposition in advance of the deposition?

MR. PRICE: Object to form.

THE WITNESS: Not in as much

Q. -- but not --
A. No, I did not see the office chart yesterday. I just saw the -- it was actually from the surgery center. It wasn't from the hospital.
Q. Okay. So he showed you the surgery center records --
A. Right.
Q. -- but not your chart?
A. Correct.
Q. Okay. Did he show you any other documents yesterday?
A. Let's see. He showed me a study from -- I don't remember the author. You know, the study from the "Green Journal."
MR. PRICE: The Iglesia?
THE WITNESS: The Iglesia study, yeah.
BY MS. METZGER:
Q. Was that the -- do you remember what year? There were a couple studies.
A. 2010.
Q. Did you see the follow-up

study by Sokol as well?

A. That's the only one he showed me.

Q. Okay. So he showed you the Iglesia study and what else?

A. I'm trying to remember what all else there was. Let's see. I think I saw the -- the information about my training for the first time today.

He said he had a copy of my certificate, but I didn't see it.

THE WITNESS: I went through my CME file and I couldn't find my copy of it, so if you have a chance, if you could mail me a copy, I'd appreciate it, and I could put it in my CME file.

MR. PRICE: I'd have to see if the defense is agreeable to doing it.

THE WITNESS: Yeah.

MR. PRICE: It's really more theirs than it is mine.

MS. METZGER: It's your certificate. It's fine with me if

A. It didn't make me go (indicating).

Q. Did it change your -- did it change your prescribing practices or your consenting practices at all?

A. I talked a little bit more about erosion rates.

Q. About erosion?

A. But I had been ever since that 2008 FDA bulletin came out, so I don't think that it changed it as much as the FDA bulletin did.

Q. Any other documents that Mr. Price showed you when he met with you yesterday? Did he show you any company documents from Johnson & Johnson or Ethicon?

A. Well, he had me sign the confidentiality agreement. I'm trying to remember what all.

Q. Well, let me ask you a different question. Did he show you any documents yesterday that we didn't look at here at the deposition today?

A. No.

Q. Did he leave any of those documents with you?

A. The only thing he left with me was the Iglesia study.

Q. Did you look at any other medical literature, discuss any other medical literature, with Mr. Price yesterday?

A. No.

Q. There were some comments that were made in the first part of the deposition about things that you had heard for the first time when you spoke with Mr. Price yesterday.

Can you refresh me about what some of those things that you heard for the first time from Mr. Price yesterday were?

A. We've gone through an awful lot of things. Would you like to refresh me about what you are --

Q. Okay. Sure.

A. -- discussing?

Q. We can go back through that. I remember, for example, I believe you

testified that you heard for the first time yesterday that -- something about the FDA regulatory process and the letter from Bryan Lisa or to Bryan Lisa from the FDA. You had seen that for the first time yesterday and heard about that for the first time yesterday; is that correct?

A. The one asking for the 522 studies?

Q. No. About the 510(k) application.

A. Oh, okay. That was the first time I had seen that, yes.

Q. Was it your opinion that your discussion with Mr. Price yesterday was intended to skew you one way or another about the integrity of the product?

MR. PRICE: Object to form.

BY MS. METZGER:

Q. And by that, I mean the Prolift product.

A. Well, I'm sure that you know that doctors are always nervous around

A. I know how that works.
Q. But I didn't get to meet with you alone yesterday.
A. I understand that.
Q. That's the difference.
MR. PRICE: Object to form.
BY MS. METZGER:
Q. Anything else about the meeting with Mr. Price yesterday? You didn't keep any notes or records of that?
A. No.
Q. Was anybody else present?
A. My wife was in the house, but she went in the bedroom, so she wasn't privy to the discussion.
Q. That was my next question. Did he meet with you in your home?
A. Yes.
Q. Okay. What time of day was that?
A. He got there right around 3:00 and I think you left at, what, 4:15 or something like that?
Q. Okay. Anything else about the conversation that you had with

lawyers. You've heard that before, I'm sure.

Q. And lawyers around doctors. That white-coat hypertension.

A. You know, I understand the way this works, and I know that everybody's always looking out for their client's own best interest. I try to be objective.

Q. Was it your impression that there was any sort of a deliberate attempt on Mr. Price's part yesterday to skew you toward testimony one way or another today?

MR. PRICE: Object to form.

THE WITNESS: I understood priorities.

BY MS. METZGER:

Q. What do you mean by that?

A. I -- I know who he's working for.

Q. All right. Anything else --

A. As well as I know who you're working for.

Q. Okay.

getting the medical device approved for marketing in the United States?

A. No.

Q. Do you know what the 510(k) process is?

A. Well, just from what I've learned here in the past two days --

Q. But you --

A. -- which isn't much.

Q. So you don't claim any particular expertise --

A. No.

Q. -- on how the Prolift may or may not have been approved at any point in its regulatory history, correct?

A. Well, I'm gathering from the letter in 2008, it was approved by its similarity to just flat pieces of mesh.

Q. But apart from -- apart from that, do you have any specialized --

A. No.

Q. -- knowledge of the approval process --

A. No.

Q. -- for --

I need to get a clean question out.

Do you have any specialized knowledge or any particular personal knowledge of how the Prolift device proceeded through the regulatory process with the FDA?

A. Not previous knowledge, no.

Q. Okay. So just what you've learned in the past couple days?

A. Yes.

Q. And you're aware -- I believe when we looked at the IFU, we looked at the component parts for the Prolift device, correct?

A. Yes.

Q. And you're aware that the Prolift kit contains a precut piece of Gynemesh PS, polypropylene mesh; is that correct?

A. Yes.

Q. And together with a set of surgical instruments; is that right?

A. Yes.

Q. The Gynemesh PS

A. She told me she was a half-a-pack-a-day smoker. It was recorded in my notes.

Q. That was the source of the information, was --

A. Yes.

Q. -- from Mrs. Flowers --

A. Yes.

Q. -- is that correct?

A. Yes.

Q. And you knew at the time that you performed the Prolift surgery on Mrs. Flowers in July of 2007 that smoking was a factor -- potential factor in poor wound healing; is that correct?

A. Yes.

Q. I assume you would have imparted that information to Mrs. Flowers?

A. I don't know that we discussed it in particular, no.

Q. Going back, just to close the loop on this FDA issue, this is Exhibit Number -- Plaintiff's Exhibit Number 14, and I'm looking at the --

looks like the third page of that exhibit. It's the May 15th letter from the FDA to Bryan Lisa at Ethicon, Inc.

Is this one of the document that Mr. Price showed you when he met with you yesterday?

A. I think so, yes.

Q. Did Mr. Price show you any of the documents that may have preceded that particular letter from FDA to Mr. Lisa?

A. I think this is the only one. I don't remember any others.

Q. Do you know what, if any, were the status of the negotiations or the discussions about Prolift between FDA and Ethicon as of the date you performed Mrs. Flowers' surgery?

A. No.

Q. You don't have any context in which to place this letter from Mr. Lisa -- or to Mr. Lisa from FDA; is that correct?

MR. PRICE: Object to form.

THE WITNESS: No.

BY MS. METZGER:

Q. Let me ask you a different way. Do you have any context for this letter dated May 15th, 2008, from the FDA to Mr. Lisa, apart from the letter itself?

MR. PRICE: Object to form.

THE WITNESS: No.

BY MS. METZGER:

Q. So you don't know what was going on before and what happened afterward?

A. No.

Q. Doctor, do you think it's fair to show you a single letter and a snapshot in time as to what was going on, on May 15th of 2008, and not give you any information about what may or may not have been going on beforehand and ask you to make a judgment about the integrity of this product?

MR. PRICE: Object to form.

THE WITNESS: It's always good to have context.

* * *

BY MS. METZGER:
Q. Okay. You weren't given that context, were you?
MR. PRICE: Object to form.
THE WITNESS: No.
BY MS. METZGER:
Q. The FDA doesn't regulate the practice of medicine, does it?
MR. PRICE: Object to form.
THE WITNESS: It doesn't regulate the practice of medicine, no.
BY MS. METZGER:
Q. So, for example, if you have Gynemesh PS soft mesh that's available to you, we've already established that that was approved for use. That's a product that was available to you, and you could use it as you wished for the indications for pelvic organ prolapse treatment; is that correct?
MR. PRICE: Object to form.
THE WITNESS: Yes.
BY MS. METZGER:
Q. And when you performed the

BY MR. PRICE:

Q. Including -- another difference is the tools that come with the Prolift kit as well, correct?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. Now, let's back up a moment to what you said about the -- the Gynemesh being the same mesh.

Because the Gynemesh had been on the market since 2002, if Ethicon was in the position to have some data on the erosion rates of the Gynemesh, would you have liked to know about those in 2007?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. And if Ethicon had some data on the severity and rate of the complications that they had seen from the Gynemesh material, would you have liked

to have seen that in the instructions for use --

MS. METZGER: Object.

BY MR. PRICE:

Q. -- with the Prolift kit?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. And if Ethicon had reports from the field of life-altering complications in patients, is that something you'd like to know in 2007?

MS. METZGER: Object to form.

THE WITNESS: Yes.

BY MR. PRICE:

Q. Is it fair to say that any data that Ethicon had received, based on the usage of the Gynemesh mesh in the field, you would have considered that data when you were implanting a Prolift?

MS. METZGER: Object to form.

THE WITNESS: Yes.